

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 25 AUG 2005

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2005/050131

International filing date (day/month/year)
13.01.2005

Priority date (day/month/year)
16.01.2004

International Patent Classification (IPC) or both national classification and IPC
C12N9/12, C07K19/00

Applicant
FRAUNHOFER GESELLSCHAFT ZUR FÖRDERUNG DER ...

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/050131

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☒ in written format
☒ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☒ furnished subsequently to this Authority for the purposes of search.
3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/050131

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 10, 13

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 10, 13
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2005/050131

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos. .

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	8, 9, 11, 12, 14, 15
	No: Claims	1-7, 16-24
Inventive step (IS)	Yes: Claims	
	No: Claims	1-9, 11, 12, 14-24
Industrial applicability (IA)	Yes: Claims	1-9, 11, 12, 14-24
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 10 and 13 so lack clarity that a meaningful search was not carried out, and no opinion will be given with regard to novelty, inventive step and industrial applicability.

Re Item IV

Lack of unity of invention

The common concept linking together the present application is "a complex of a component A and a component B wherein A comprises a binding domain for cellular surface structures and B has kinase properties. Said concept is neither novel nor inventive. Such complexes are well known in the art: Indeed any known complex involving a kinase might be novelty destroying, see also the complexes disclosed by in alia D1-D4.

Hence, any particular complex, i.e. the association of a particular component A and a particular component B, represents a single invention. In the present at least claims 3183 different "inventions" could be identified.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

- D1: US-A-5 670 324 (LITTMAN DAN ET AL) 23 September 1997 (1997-09-23)
D2: US 2002/176851 A1 (SEED ET AL.) 28 November 2002 (2002-11-28)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2005/050131

D3: US-A-5 935 835 (MARSHALL LISA ET AL) 10 August 1999 (1999-08-10)

D4: US 2000/151684 A1 (MAYER ET AL.) 17 October 2002 (2002-10-17)

D1 discloses chimeras i.e complexes of a kinase (tyr kinase) and a binding domain for a cellular surface structure and the use of such complexes in medicine (abstract, figures, col. 1, col. 2, claims).

1. In view of D1 or D2 or D3 or D4 claims 1-7, 16-24 do not meet the requirements of Art. 33(2) PCT.
Furthermore said claims are so broadly and vaguely drafted that nearly any known naturally occurring complex, involving a kinase, falls under the scope of the claims. Therefore said natural complexes are novelty destroying.
It is to be noted that even if novelty could be restored the claims would probably still lack inventive step Art. 56 EPC.
2. Claims 8, 9, 11, 12, 14, 15 represent an arbitrary selection of a particular component A and B, among equally suitable components. Inventive step could be acknowledged only if a surprising effect for the skilled person can be shown. This is not the case in the present application.
Thus, said claims do not meet the requirements of Art. 33(3) PCT.

Additional remark:

3. It is to be noted the claims do not meet the requirements of Art. 5 PCT and Art. 6 PCT.
The claims seem to be drafted as mere "laundry lists" devoid of any real technical feature. Furthermore, it seems also that apparently none of the claimed complexes is suitable for use in the "medical use claims" (no evidence shown in the description as to the alleged effects).
4. The attention of the applicant is drawn to the fact that a reply to this opinion is only expected if he intends to file a chapter II demand.